MMRE

Medical Marijuana Research and Education

Research & Education Projects

2018-2019 Guidelines

Submission Deadlines:

Letter of Intent (optional): March 15, 2018

Full Application: April 12, 2018

Award Announcements: June 7, 2018

Project Start Date: July 1, 2018

Project End Date: June 30, 2019

Submit to: Bobbie.McKee@moffitt.org
Questions: Bobbie.McKee@moffitt.org
Website: http://mmreboard.org/

Purpose:
The State of Florida's Medical Marijuana Research and Education (MMRE) Program invites investigators from across the state to apply for funding for research and education projects. Proposals must meet one of the following two objectives of the Coalition:

1. Identify and prioritize the research eligible to be conducted through the Coalition to develop a comprehensive evidence base on the short- and long-term health effects of marijuana for medical use, addressing the key gaps in the evidence base.
2. Build infrastructure to increase knowledge and understanding of current evidence on the short- and long-term health effects of marijuana use among health care professionals, policy makers, growers, marijuana dispensaries/pharms, public, patients and caretakers.

The proposed projects are expected to ultimately result in additional grant applications to other sponsors or lead to clinical research studies.

Areas of Interest:
Topics meeting either the research or education objectives may include, but are not limited to the following:

1: Research
Projects aimed at developing a comprehensive evidence base on the short- and long-term health effects of marijuana for medical use, addressing the key gaps in the evidence base.

All research conducted through the Coalition must be in compliance with the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA) policies and regulations. Research conducted will, in addition, be approved by relevant Institutional Review Board/Institutional Animal Care and Use Committee (IRB/IACUC).

1a. Observational/Survey Research:

- Evaluate past history and current medical marijuana use, indication for use, bioavailability, potential beneficial and harmful health effects of using different forms of marijuana (such as inhaled [smoked or vaporized], tincture, sprays, suppositories, oils), among individuals prescribed medical marijuana.
- Document and evaluate statewide referral patterns, reported indications, benefits and adverse events with use of medicinal marijuana as a function of age, gender, race, locale, co-morbidities, other risk exposures, socio economic status and provider.
- Characterize public safety concerns related to medical marijuana use and evaluate existing quality assurance, safety, packaging and current standards for dispensing and patient education regarding medical marijuana products.
- Perform ecological evaluation contrasting statewide cause-specific death and morbidity rates in the calendar year preceding and year following passage of the law.
- Utilize the State of Florida Medical Marijuana Registry to characterize the health effects of medical marijuana dose and mode of administration on related overdoses and poisonings, traffic accidents, work productivity, depression, fatigue and other health endpoints.

1b. Education to improve knowledge of Health Professionals and the Public:

- Survey State of Florida health care providers on current state of knowledge regarding state medical and federal medical marijuana laws, perceived indications for medical marijuana, related evidence base, benefits and risks, barriers and facilitators to referral.
- Identify gaps in medical marijuana knowledge and related skills of health care and public health professionals and develop education programs to address these gaps.

- Evaluate public knowledge and understanding of known risks and benefits of medical and recreational marijuana use. Identify educational needs, develop educational programs and evaluate the impact over time.

1c. Laboratory Research:

- Apply state-of-the art techniques to screen phytochemical components of marijuana (and additives) and validate the potential targets *in vitro* and *in vivo* to inform potential use in specific medical use indications.

- Provide laboratory based evidence to determine whether medical marijuana use synergizes or antagonizes with prescribed drugs. Investigate the molecular mechanisms of these interactions and their clinical implications.

1d. Clinical Research:

- Informed by laboratory and preclinical studies, investigate the pharmacokinetic and pharmacodynamic properties of medical marijuana, modes of delivery, different concentrations, in various populations, including the dose–response relationships of marijuana to other cannabinoids as monotherapies and in combination with standard treatment modalities.
- Conduct well-controlled phase I-III trials on the potential health effects , including psychosocial impact of using different forms of marijuana, such as inhaled (smoked or vaporized), tincture, sprays, suppositories, oils etc.) targeting specific unstudied and understudied health endpoints.

1e. Health Policy and Health Economics Research:

- Identify models, including existing state marijuana policy models, for sustainable funding of national, state, and local public health surveillance systems.
- Investigate the economic impact of medical marijuana use on state public health and health care systems, health insurance providers, and patients.

2: Professional and Public Education

Propose educational projects to increase knowledge and understanding of current evidence on the short- and long-term health effects of marijuana use among health care professionals, policy makers, growers, marijuana dispensaries/pharms, public, patients and caretakers. Areas of interest include but are not limited to:

2a. Health Care Guidelines

- Coalesce and organize national resources, including clinical practice guidelines [National Institute of Health(NIH) -National Institute of Drug Abuse, National Cancer Institute(NCI), National Institute of Ageing (NIA), American Society of Clinical Oncology (ASCO), American Academy of Pediatrics (AAP), American Psychological Association (APA), etc.], and develop additional resources to improve knowledge on medical marijuana, targeting medical, pharmacological, nursing, paramedical and other health care professional groups in the state of Florida.
- Provide access to the most up-to-date research and clinical guidelines resources to guide clinical practice from national sources, including research results conducted through the Coalition.
    - NCI: https://www.cancer.gov/about-cancer/treatment/cam/hp/cannabis-pdq
    - NIDA: https://www.drugabuse.gov/publications/research-reports/marijuana
      https://www.drugabuse.gov/publications/drugfacts/marijuana

2b. Research Quality

Conduct an annual, interactive workshop of multi-disciplinary leaders, to develop research standards and benchmarks to guide and ensure the production of high-quality medical marijuana research. Workshop objectives will include, but will not be limited to:

- The development of a minimum dataset for observational and clinical studies, standards for research methods and design, and guidelines for data collection methods.
- Adaptation of existing research-reporting standards to the needs of medical marijuana research.
- The development of uniform terminology for clinical and epidemiological medical marijuana research.
- The development of standardized and evidence-based question banks for clinical research and public health surveillance tools.
- Determining the capacity to collect and reliably interpret data from diagnostic classification codes in administrative data (e.g., International Classification of Diseases-10).
- The establishment and utilization of state-based testing facilities to analyze the chemical composition of marijuana and products containing components of marijuana or other cannabinoids.
- The establishment and utilization of standardized protocols to analyze the chemical composition of marijuana and products containing components of marijuana.
- The development of novel diagnostic technologies that allow for rapid, accurate, and noninvasive assessment of marijuana exposure and impairment.
- Strategies for surveillance of harmful effects of marijuana for therapeutic use.

2c. Public Education

Coalesce and organize national resources (NIH-NIDA,NCI,NIA; ASCO, AAP, APA, ANA etc), and develop additional resources to improve current knowledge of the general public, patients and caretakers in the State of Florida on medical marijuana use (both beneficial and harmful effects) for specific indications.

Provide access to the most up-to-date research and clinical guidelines resources that inform clinical practice from national sources.

- https://www.cancer.gov/about-cancer/treatment/cam/patient/cannabis-pdq
- https://teens.drugabuse.gov/drug-facts/marijuana

Eligibility

For Objective 1 topics (research), applicants should hold an academic position at a university or research institution in Florida.

For Objective 2 topics (education), applications should hold either an academic position or a position of authority requisite with the proposed work such as non-profit program director or hospital management. Position must be held at a university, research institution, non-profit, hospital or other organization within Florida.

Review Process

All applications will be reviewed and scored by a multidisciplinary team of research scientists, educators and clinicians termed the Coalition Faculty Steering Committee (CFSC) and ad hoc reviewers as necessary.

Projects will be reviewed on the strength of their scientific merit, innovation, measureable deliverables/milestones, potential impact, adherence to the areas of focus, qualifications of the PI, and potential to result in extramural funding or lead to informing clinical trial development or new guidelines.

The CFSC will submit final critiques and scores to the Coalition Board of Directors for final award decision and funding.

Letter of Intent

A letter of intent is encouraged but not required. The letter should be no more than 1 page long and include:

- Name(s) of Principal Investigator(s)
- Preliminary list of all key personnel (non-binding)
- Objective (research or education) and area of interest
- Preliminary project title
- Preliminary project abstract
- Participating location(s)

Application Guidelines

Applicants are limited to only one application submission as Principal Investigator. However, applicants may be listed as co-investigators and collaborators on additional applications.

1. **Proposal Requirements Summary:**
   - Face Page and Abstract (NIH format)
   - Key Personnel List
   - NIH Biosketches to include on-going and pending internal and external support for Principal Investigator(s) and key personnel
   - Budget (see below for template information)
   - Budget Justification including qualifications of Principal Investigator(s) (Maximum of 3 pages)
   - Research or Education Plan (Maximum of **5 pages**)
   - References (no page limit)

2. **Specific Application Instructions:**
   - Use NIH format: Arial 11 point black font, single-spaced with all text showing and 0.5 inch margins (all sides)
   - The Principal Investigators' last names should be shown in the header of all application pages

3. **Budget**
   - Project Period: 07/1/2018 to -6/30/19
   - No cost extensions (NCEs) are discouraged. If overall funds are not permitted by the State to be carried forward, then NCEs will not be approved.
   - Applications may request up to $200,000 in Direct Costs ($230,000 Total Costs)
   - F&A of 15% is applied to Total Direct Costs.
   - Use of the MMRE Budget Template and Budget Justification Form are required. A PDF copy of the forms are a required component of the application file is. The template can be found on the MMRE website, http://mmreboard.org/. Please contact Dr. Bobbie McKee (Bobbie.McKee@moffitt.org) with questions.

Overview of Allowable and Unallowable Costs:	
Allowable	**Unallowable**
• Effort and Salary (including PI) • Research supplies and animal expenses • Technical assistance • Registration fees at scientific meetings • Publication costs, including reprints • Shared resource costs • Special fees (pathology, photography, etc.) • Stipends for graduate students and postdoctoral assistants if their role is to promote and sustain the project presented by the investigator • Equipment costing less than $2,000 (Special justification is necessary for items exceeding this amount and must be included in the proposal budget and justified for specific research purposes) • In special circumstances computer purchases justified for specific scientific purposes may be allowed at the beginning of the award with prior approval. All equipment must be budgeted at the time of the application • Tablets and e-readers for specific scientific purposes and must be justified and budgeted in the application. Data plans, if needed must also be justified. NOTE: Data plan costs for tablets and e-readers are not supported by the MMRE. • Domestic travel is allowable if necessary to complete the goals of the project and must be justified and budgeted in the application and approved by the review committee.	• Secretarial/administrative salaries • Tuition • Foreign travel • Honoraria and travel expenses for visiting lecturers • Books and periodicals • Membership dues • Office and laboratory furniture • Office equipment and supplies • Most computer purchases • Rental of office or laboratory space • Recruiting and relocation expenses • Non-medical services to patients • Per-diem charges for hospital beds • Construction, renovation, or maintenance of buildings/laboratories

4. Research or Education Plan

Describe collaborative research project relating to cancer. **Maximum 5-page total for Research or Education Plan to include the following:**

- **Specific Aims**: List the broad, long-term objectives that this research or education project is intended to accomplish. Clearly state the hypothesis to be tested. Include deliverables (specific steps and/or outcomes) and milestones (timing) for each of the specific aims.
- **Background and Significance:** Briefly present the background leading to the present research or education project, critically evaluating existing knowledge, and specifically identify the gaps that the project is intended to fill.
- **Proposed Research:** Summarize the study design and methods that the project will employ. Explain whether and how the proposed work will lead to future funding.

Proposed Education Program Development and Evaluation: Summarize the development, testing and refinement of already-developed education programs or new education programs on outcomes of knowledge and behavior, applicable to a specific target populations or implementation or dissemination into diverse settings.

- **Collaboration Plan:** If applicable, briefly describe the role that each Center will play in the project, and how this strengthens the project.

5. **References**
   Complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed separately or at the end of the research or Education plan (no page limit).

Other Considerations:

1. **Statistical Review of Applications**
   Investigators proposing research projects should seek input from a biostatistician unless the project is only a lab-based, early developmental study. If unavailable at your institution, the Moffitt Biostatistics Core is available to provide this fee-based service. Please make biostatistics requests at http://moffittnetapps.moffitt.org/apps/BiostatisticsAssistanceForm/Default.aspx, or contact Dr. Richie Reich at Richie.Reich@moffitt.org for more information.

2. **Additional Approvals**
   If awarded, the PI must secure:
   - Institutional Review Board approval if research involves human subjects
   - IACUC approval if research involves animals
   - Approval of project by U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA), as appropriate.

   Note: It is the investigator's responsibility to notify Moffitt's Office of Sponsored Research after DEA, FDA, IRB/IACUC approval has been received to release funds.

3. **Submission**
   All PIs should follow their organization's pre-award policies and procedures to obtain institutional approval prior to submission of applications to the MMRE program. Institutional Official signature is required on the face page of the application. The submitting institution should submit the completed application as a single PDF file to the MMRE Program (Bobbie.McKee@moffitt.org). **The due date is April 12, 2018, by 5 pm**.

4. **Awardee Obligations:**
   - **Progress Report** - For at least five years following award receipt, awardees will complete a progress report annually. These reports are completed via email, average 2-3 pages, and describe: 1) pilot project progress and results; 2) all publications and funding resulting from the award. Reports should be submitted to Dr. Bobbie McKee, Bobbie.McKee@moffitt.org.

   - **Acknowledgement of Funding:** Awardees must acknowledge the State of Florida Medical Marijuana Research & Education Coalition in any publications or presentations by including the statement:

     "The work that is reported in this publication was supported by the State of Florida Medical Marijuana Research & Education Coalition."

   - **Peer-reviewed proposal submission:** One goal of the pilot study is to submit an extramural grant or clinical study within eighteen months of the award ending.

   - **No-cost extensions:** Funds are to be expended within the approved project period and budget. No-cost extension requests are discouraged but will be considered on a case-by-case basis. Any approval of a no-cost extension is contingent on the State allowing for carryforward of funds for this program into the next fiscal year.

Submission Deadlines:
Letter of Intent (optional): March 15, 2018
Full Application: April 12, 2018
Award Announcements: June 7, 2018
Project Start Date: July 1, 2018
Project End Date: June 30, 2019

Submit to: Bobbie.McKee@moffitt.org
Questions: Bobbie.McKee@moffitt.org
Website: http://mmreboard.org/

NOTE: All awards in response to this funding opportunity are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this funding opportunity, all applicants acknowledge and consent to this condition.